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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,249	09/09/2003	Kim R. Rogers	ROGERS1	4045
1444 7590 01/05/2007 BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			EXAMINER NAFF, DAVID M	
			ART UNIT	PAPER NUMBER
			1657	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/657,249

Applicant(s)

ROGERS ET AL.

Examiner

David M. Naff

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 2-6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 7-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

An amendment of 10/5/06 in response to an office action of 6/14/06 amended claims 1 and 7-10, and added new claims 11-18.

Claims in the application are 1-18.

5 Claims 2-6 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 4/5/06.

Claims examined on the merits are 1 and 7-18.

10 The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C.

15 112:

20 The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

25 Claims 1 and 11-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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Adequate support is not found in the specification for "single sol-gel" bridging lines 3 and 4 of claim 1. The specification nowhere recites "single". It is suggested the claim recite "a sol-gel" as recited in the specification.

Claim Rejections - 35 USC § 112

Claims 1 and 7-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and claims dependent thereon are unclear by "single sol-gel" in claim 1 being uncertain as to meaning and scope. It is uncertain as to whether this is a one kind of sol-gel, one vessel containing a sol-gel or one sol-gel in a series of sol-gels. The specification fails to distinguish the sol-gel as being single and not single.

Claim 7 and claims dependent thereon are confusing by claim 7 in the last line not having clear antecedent basis for "the test".

Claim 10 is unclear how the bag is defined by being opened. The bag being opened to expose the acetylcholinesterase to the inhibitor is involved in a process of using the detector. The detector does not contain the bag while open before use in a process of detecting. If the claim intends the bag to be capable of being opened to expose the acetylcholinesterase to the inhibitor, the claim should be amended by inserting --- capable of being --- after "is" in line 3.

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Claim 15 is confusing by not having antecedent basis for "the sol-gel particles". Claim 1 does not require sol-gel particles.

Claim Rejections - 35 USC § 103

Claims 16 and 18 are rejected under 35 U.S.C. 103(a) as being
5 unpatentable over Kok et al (J. Biomater. Sci. Polymer Edn, Vol 12,
No. 11, pp. 1161-1176 (2001)).

The claims are drawn to a detector for detecting at least one of organophosphorus or carbamate consisting of acetylcholinesterase immobilized in a sol-gel or membrane, wherein the acetylcholinesterase
10 is inhibited by the organophosphorus or carbamate.

Kok et al disclose acetylcholinesterase and choline oxidase immobilized in a membrane for use as a biosensor.

It would have been obvious to omit choline oxidase from the membrane of Kok et al when the function of the choline oxidase is not
15 needed, and the resulting acetylcholinesterase immobilized in a membrane is a detector that is the same as presently claimed. The acetylcholinesterase of Kok et al will inherently be inhibited by organophosphorus or carbamate compounds.

Claim Rejections - 35 USC § 103

20 Claims 1, 14 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kok et al in view of Stanford et al (7,008,524 B2) and Avnir et al (5,650,311) (newly applied).

The claims require the acetylcholinesterase to be immobilized in a sol-gel.

25 Kok et al is described above.

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Stanford et al disclose acetylcholinesterase immobilized in a sol-gel film on electrodes. For example, see claim 9.

Avnir et al disclose entrapping enzymes in a sol-gel glass (paragraph bridging cols 4 and 5) for use as a biosensor (col 5, lines 14-15). The sol-gel containing the immobilized enzyme can be formed in a tube (col 7, line 17).

It would have been obvious to substitute for the membrane of Kok et al a sol-gel as suggested by Stanford et al for immobilizing acetylcholinesterase. It would have been obvious to immobilize the acetylcholinesterase in a sol-gel without electrodes as suggested by Avnir et al immobilizing enzymes in a sol-gel that can be used without the presence of electrodes. The sol-gel of Avnir et al can be considered a single sol-gel as in claim 1. It would have further been obvious to form the sol-gel in a tube as suggested by Avnir et al forming the sol-gel in a tube.

Claim Rejections - 35 USC § 103

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claim 1 above, and further in view of Charych et al (6,485,987 B1) (newly applied).

The claim requires the sol-gel to be a glass prepared from tetramethylorthosilicate.

Kok et al, Stanford et al and Avnir et al are described above.

Charych et al disclose preparing a sol-gel glass from tetramethylorthosilicate (paragraph bridging cols 2 and 3) for use as a detection means (col 3, line 43).

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When modifying Kok et al as suggested by Stanford et al and Avnir et al as set forth above, it would have been obvious to produce the sol-gel as a glass using tetramethylorthosilicate as suggested by Charych et al.

Claim Rejections - 35 USC § 103

Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claim 11 above, and further in view of Khue et al (5,624,831) (newly applied).

The claims required the acetylcholinesterase in the sol-gel to be stabilized with a sugar, which can be trehalose.

Kok et al, Stanford et al, Avnir et al and Charych et al are described above.

Khue et al disclose that trehalose is a sugar used to stabilize enzymes (col 3, line 31), and using trehalose to produce stabilized acetylcholinesterase (paragraph bridging cols 3 and 4).

When modifying Kok et al as suggested by Stanford et al, Avnir et al and Charych et al as set forth above, it would have been obvious to use trehalose to stabilize acetylcholinesterase as suggested by Khue et al.

Claim Rejections - 35 USC § 103

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claim 1 above, and further in view of Magdassi et al (6,303,149 B1) (newly applied).

The claim requires the sol-gel of claim 1 to be particles from 230-400 mesh.

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Kok et al, Stanford et al and Avnir et al are described above.

Magdassi et al disclose sol-gel particles containing enzymes (col 2, lines 38 and 44-56, and col 3, lines 34-67).

When modifying Kok et al as suggested by Stanford et al and Avnir et al set forth above, it would have been obvious to produce the sol-gel as particles as suggested by Magdassi et al. Selecting a preferred particle size would have been a matter of choice within the skill of the art.

Claim Rejections - 35 USC § 103

10 Claims 7, 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kok et al in view of Strobel et al (5,766,473).

The claims require a detector as required by claim 16 wherein the sol-gel or membrane is packaged so that when the package is opened the acetylcholinesterase is exposed to ambient conditions so the test is conducted. Claim 10 requires the package to be a semipermeable polyethylene bag, which is opened to expose the acetylcholinesterase to the inhibitor.

Koke et al is described above.

20 Strobel et al disclose storing enzyme-loaded membranes in a polyethylene bag (col 33, lines 43-45).

It would have been obvious to store the membrane containing acetylcholinesterase disclosed by Kok et al in a polyethylene bag as suggested by Strobel et al storing an enzyme-containing membrane in a polyethylene bag. The polyethylene bag is inherently semipermeable and capable of being opened as in claim 10.

Claim Rejections - 35 USC § 103

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 7, 9 and 10 above, and further in view of Stanford et al and Avnir et al.

5 The claim requires the acetylcholinesterase to be immobilized in a sol-gel.

Kok et al, Strobel et al, Stanford et al and Avnir et al are described above.

10 When modifying Kok et al as suggested by Strobel et al, it would have been obvious to substitute for the membrane of Kok et al a sol-gel as suggested by Stanford et al and Avnir et al for immobilizing acetylcholinesterase.

Response to Arguments

15 The deletion of membrane from claim 1 does not overcome the rejection since Stanford et al and Avnir et al suggest a sol-gel as claimed in place of the membrane.

20 Applicants urge that Strobel et al is packaging an enzyme reaction system contained by a membrane, and not a membrane containing acetylcholinesterase. However, the package of Strobel et al would have been expected to function for storage of the acetylcholinesterase-containing membrane of Kok et al in the same type of way it functions to store the enzyme-containing membrane of Strobel et al.

25 Applicants urge that Stanford et al require a hybrid film on electrodes. However, when Avnir et al is considered, it would have

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been obvious that the electrodes of Stanford et al can be omitted when immobilizing acetylcholinesterase in a sol-gel.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

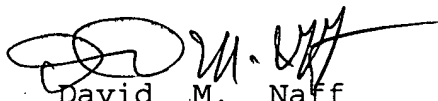
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


David M. Naff
Primary Examiner
Art Unit 1657

DMN

15 12/22/06